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Official Contact: Tsuyoshi Sugino – Regulatory Affairs Manager

Proprietary or Trade Name: Neo-Servo *i* Atom Infant Incubator Model 102

Common/Usual Name: Neonatal Incubator

Classification Name/Code: FMZ – neonatal incubator
CFR 880.5400

Device: Neo-Servo *i* Atom Infant Incubator Model 102

Predicate Devices: Atom Model V-2200 – K061856

Device Description:
The Neo-Servo *i* Atom Infant incubator Model 102 consists of a hood, a main body, a control panel and is offered with or without a stand with casters. The Model 102 incorporates two (2) modes of control: air (manual control) and baby (servo control).

The Model 102 incorporates the sensors (humidity and temperature) inside the hood monitor the air conditions inside the hood. These are connected to the Sensor module. It is equipped with an incubator air temperature control function to circulate air containing the heat generated b the heater attached to the conditioning chamber inside the hood by means of a fan in order to.maintain the incubator air temperature at a fixed level. It is equipped with a skim temperature control function o maintain the infant's skin temperature at a fixed level in response to the patient's temperature as measured by the skin probe. There are optional humidity chamber and x-ray cassette tray.

There are 2 functional modes:

1. Skin temperature control mode referred to as "Servo Control Mode"
2. Air temperature control mode referred to as "Manual Control Mode"

Indications for Use:
The Neo-Servo *i* Atom Infant Incubator Model 102 is a closed-type incubator for newborns and premature neonates. It is mainly intended for temperature control in neonatal hypothermia, observation and examination in newborn nurseries, prevention of body temperature drop shortly after delivery, and pre-operative and post-operative intensive care in neonatal surgery. The incubator is provided with a function to control the infant's skin temperature.

Environment of Use: Hospitals, delivery suites, NICU

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Summary of substantial equivalence

	Proposed **Neo-Servo *i*** **Atom Infant Incubator Model 102**	**Predicate** **K061856** **Atom V-2200 Infant Incubator**
Indications for Use	The Neo-Servo *i* Incubator Model 102 is a closed-type incubator for newborns and premature neonates. It is mainly intended for temperature control in neonatal hypothermia, observation and examination in newborn nurseries, prevention of body temperature drop shortly after delivery, and pre-operative and post-operative intensive care in neonatal surgery. The incubator is provided with a function to control the infant's skin temperature.	The V-2200 infant incubator is intended to keep premature neonates or infants in a warm environment which is covered by a hood and isolated from ambient air and of which internal air temperature and humidity, are controlled.
Environment of use	Hospital, delivery suites, NICU Not for transport	Hospital, delivery suites, NICU Not for transport
Patient Population	Infant and neonates $\leq$ 10 kg	Infant and neonates $\leq$ 10 kg
Features and Performance Characteristics		
Overall dimensions	With HL stand 100(D) x 60(W) x 138-158(H) cm Mattress – 65(W) x 36.5(D) x 2(T) cm Adjustable height of 86 – 106 cm from the floor to the mattress top	With HL stand 109 (D) x 61(W) x 133-153(H) cm Mattress – 74(W) x 36(D) x 2(T) cm
Weight	90 kg	107.5 kg
Major components	Hood Main body Control unit	Hood Main body Control unit
Power	AC 120V	AC 120 V
Operating conditions	Ambient - 20-30 °C RH - 30-75%	Ambient - 20-30 °C RH - 30-75%
Storing conditions	Ambient - 0-50 °C RH - 30-75%	Ambient - 0-50 °C RH - 30-75%
Maximum load capacity	IV Pole ~ 10 kg Drawer ~ 3kg	IV Pole ~ 5kg Drawer ~ 5kg MF Rail ~10kg

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	Proposed **Neo-Servo *i*** **Atom Infant Incubator Model 102**	**Predicate** **K061856** **Atom V-2200 Infant Incubator**
Features and Performance Characteristics (continued)		
Accessories / optional components	Skin Temperature Probe Electrostatic Air filter Access port covers X-ray cassette tray (optional) Humidifier chamber (optional)	Skin Temperature Probe Electrostatic Air filter Access port covers X-ray cassette tray (optional) Humidifier chamber (optional) Optional only on V-2200 Pulse oximeter Oxygen sensor
Control modes	Manual and Servo	Manual and Servo
Skin Temperature Setting Range	Servo 34 – 37.5 °C (override mode 37.6 – 38.0 °C)	Servo 34 – 37.5 °C (override mode 37.6 – 38.0 °C)
Incubator air temperature	23 - 39 °C (including override)	23 - 39 °C (including override)
Display range	Skin - 30.0 - 42 °C Accuracy - ± 0.3 °C Air - 20.0 – 42.0°C Accuracy - ± 0.3 °C	Skin - 30.0 - 42 °C Accuracy - ± 0.3 °C Air - 20.0 – 42.0°C Accuracy - ± 0.3 °C
Heater output	0 – 100% in 10 increments	0 – 100% in 10 increments
Warm-up time	≤ 60 min @ 25°C	≤ 60 min @ 25°C
Alarms	High temperature Set temperature Skin temperature	High temperature Set temperature Skin temperature
Humidity	In Servo mode	In Servo mode
Humidity setting range	40 – 95% RH	40 – 95% RH
Humidity display	15 – 99% RH	15 – 99% RH
Continuous humidity	~ 8 hours	~ 8 hrs
Alarms	Humidity sensor Low water level No water Humidity chamber off Set humidity	Humidity sensor No water Humidity chamber off Set humidity
Oxygen supply	Maximum concentration ≥ 65% @ 10 Lpm	Maximum concentration ≥ 65% @ 10 Lpm
Environment CO_2 concentration in the hood	< 0.4% at center of mattress at 750 ml/min	< 0.4% at center of mattress at 750 ml/min
Oxygen supply	Maximum concentration ≥ 65% @ 10 Lpm	Maximum concentration ≥ 65% @ 10 Lpm
Other alarms	Fan System failure Power failure	Fan System failure Power failure

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Other functions	Not offered Not offered	SpO2 monitoring (optional) Oxygen (FiO2) control (optional)
Mattress	Tilting	Titling
X-ray cassette	Optional	Optional
Performance testing		
Performance testing has been performed per the following standards	IEC 60601-1 (1995) – Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 2 IEC 60601-1-2 : 2001– Medical Electrical Equipment - Part 1-2: General requirements for Safety-Collateral standard: Electromagnetic compatibility Requirements and tests (Edition 3) IEC 60061-2-19 (1996) – Amendment 1 - Medical Electrical Equipment - Part 2: Particular Requirements for Safety of Baby Incubators.	IEC 60601-1 (1995) – Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 2 IEC 60601-1-2 : 2001– Medical Electrical Equipment - Part 1-2: General requirements for Safety-Collateral standard: Electromagnetic compatibility Requirements and tests (Edition 3) IEC 60061-2-19 (1996) – Amendment 1 - Medical Electrical Equipment - Part 2: Particular Requirements for Safety of Baby Incubators.

Substantial Equivalence Rationale

The Neo-Servo *i* Atom Infant Incubator Model 102 is viewed as substantially equivalent to the predicate device because:

Indications –
- Identical to predicate – Atom V-2200 Infant incubator - K061856

Technology –
- Identical technology and design – Atom V-2200 Infant incubator - K061856

Materials –
- The materials in patient contact are identical to the predicate K061856

Environment of Use –
- Identical to predicate – Atom V-2200 Infant incubator - K061856

Performance Testing –
Performance testing has been performed according to recognized standards and the proposed device met and passed all testing criteria.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Atom Medical Corporation
C/O Mr. Paul Dryden
Promedic, Incorporated
24301 Woodstage Drive
Bonita Springs, Florida 34134

DEC 2 2 2010

Re: K102710
Trade/Device Name: Neo-Servo I Atom Infant Incubator Model 102
Regulation Number: 21 CFR 880.5400
Regulation Name: Neonatal Incubator
Regulatory Class: II
Product Code: FMZ
Dated: November 22, 2010
Received: November 23, 2010

Dear Mr. Dryden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K102710

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Indications for Use Statement

510(k) Number: _____ (To be assigned)

Device Name: Neo-Servo *i* Atom Infant Incubator Model 102

Indications for Use:

The Neo-Servo *i* Atom Infant Incubator Model 102 is a closed-type incubator for newborns and premature neonates. It is mainly intended for temperature control in neonatal hypothermia, observation and examination in newborn nurseries, prevention of body temperature drop shortly after delivery, and pre-operative and post-operative intensive care in neonatal surgery. The incubator is provided with a function to control the infant's skin temperature.

Environment of use – Hospitals, delivery suites, NICU

Prescription Use XX (Part 21 CFR 801 Subpart D) **or** **Over-the-counter use __** (21 CFR 807 Subpart C)

Rld C. Chyn 12/20/10

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K102710